



GDP Webinar

Data Integrity at GDP

Date:

Monday, 14 September 2020, 14.00 – 15.30 h CEST

Speaker:

David Abraham, Quality Resource Solutions Associates

DATA INTEGRITY



ECA has entrusted
CONCEPT HEIDELBERG with the
organisation of this webinar.

CONCEPT HEIDELBERG GmbH
Rischerstrasse 8
69123 Heidelberg, Germany
Phone +49 (0) 6221 - 84 44 0
Fax +49 (0) 6221 - 84 44 64
info@concept-heidelberg.de

Background

The issue surrounding data integrity has now been with us for several years since regulatory bodies such as the Medicines and Healthcare products Regulatory Agency (MHRA), the U.S. Food and Drug Administration (FDA), the World Health Organization (WHO) and the European Medicines Agency (EMA) started to raise concerns to the industry. The application of data integrity is integral to Good Distribution Practice (GDP) and as complexities of pharmaceutical distribution continue to present new challenges throughout the supply chain to ensure medicinal products are not compromised. As regulators intensify their focus in data integrity it is important that managers, supervisors and Responsible Persons understand how data generation and flow are vital to ensure robustness within the supply chain and integral to GDP processes and systems.

Educational Objectives

This webinar aims to give participants a compact overview on how data integrity interacts with GDP as well as understanding expectations of current guidance.

The following topics will be covered:

- Understanding data integrity
- The differences between data and data integrity
- Guidance and industry standards
- The principles of data integrity
- Data flow in GDP
- Integrating data integrity governance on GDP

Target Audience

The webinar is aimed at all personnel involved at all levels within the following industries: Pharmaceutical manufacturers (e.g. logistics and QA), drug wholesalers, logistics companies, external warehouses, extended service providers offering services in support of the distribution of medicinal products.

Speaker



David Abraham, Quality Resource Solutions Associates

David has extensive experience in both business and Quality Management. David's background has seen him working within Pharmaceutical and Healthcare arena from print and packaging, distribution as well as pharmaceutical manufacturing organizations; designing, developing, implementing, maintaining and improving business processes and Quality Management Systems in line with the application of both GMP and GDP. Additionally he has provided key inputs in the development of a number of industry guidance and standards and was project leader in the development of the PS 9000 series of standards and guidance. His work continues to see his engagement across the industry, supply chain and training organisations providing resource, awareness, training and consulting in quality management and the application of GXP as well as continue to provide input on a number of technical committees at a national, European and International level.

Fees (plus VAT)

Single participation: € 249,- for ECA Members
Single participation: € 299,- for non-ECA Members
(This fee does not include the ECA Membership.
You will find more about the ECA Membership at <https://www.gmp-compliance.org/about-the-academy>).

Participation of a Group

You have colleagues who also want to participate in the webinar? Then register yourself and your colleagues as a GROUP! You can view the webinar either together (e.g. in a conference room, etc.) or also each individually on your own PC.

Group Participation (fee per person):

3-10 Persons EUR 254,15
11-20 Persons EUR 224,25
more than 20 Persons EUR 194,35

Registration

By mail, fax, e-mail or online on the Internet at <https://www.gmp-compliance.org/>. In order to avoid misunderstandings, please indicate the exact address and the full name of the participant. You will receive your access data by e-mail in due time prior to the event.

Technical Requirements

For our webinars, we use Cisco WebEx, one of the leading suppliers of online meetings. At <http://www.webex.com/test-meeting.html> you can check if your system meets the necessary requirements for the participation at a WebEx meeting and at the same time install the necessary plugin. Please just enter your name and email address for the test. If the installation is not possible because of your rights for the computer system, please contact your IT department. WebEx is a standard nowadays and the necessary installation is fast and easy.

Presentation/Certificate

The presentation will be made available to you prior to the Webinar as a PDF file. After the Webinar, we will automatically send you a certificate of participation.

Organisation/Contact

CONCEPT HEIDELBERG, P.O. Box 10 17 64, D-69007 Heidelberg,
Tel. +49(0)6221/84 44-0, Telefax +49(0)6221/84 44 34
info@concept-heidelberg.de, www.gmp-navigator.com

Do you have any questions?

For questions regarding content please contact:
Dr Markus Funk, phone +49(0)6221/ 84 44 40
Email: funk@concept-heidelberg.de

For questions regarding organisational aspects please contact:
Mr Niklaus Thiel, phone +49(0)6221/84 44 43
Email: thiel@concept-heidelberg.de

Registration for the Webinar: Data Integrity at GDP on Monday, 14 September 2020, 14.00 – 15.30 h CEST

Speaker: David Abraham

Please fax to CONCEPT HEIDELBERG, +49 (0)6221/84 44 34 or you register online at www.gmp-compliance.org.

Please tick:

- Single Participation**
- Group Participation**
 - 3-10 Persons
 - 11-20 Persons
 - more than 20 Persons

Important:
Deadline is 09.00 a.m.
on 14 September 2020

Title, First Name, Last Name

Company

Department

VAT ID No. (mandatory)

Street

Postal Code/City

Phone

Fax

E-Mail (mandatory for your registration)

General Terms and Conditions

If you cannot attend the conference you have two options:

1. We are happy to welcome a substitute colleague at any time.
2. If you have to cancel entirely we must charge the following processing fees:
Cancellation until 2 weeks prior to the conference 10 %, until 1 week prior to the conference 50 %, within 1 week prior to the conference 100 %.

CONCEPT HEIDELBERG reserves the right to change the materials, instructors, or speakers without notice or to cancel an event. If the event must be cancelled, registrants will be notified as soon as possible and will

receive a full refund of fees paid.

Terms of payment: Payable without deductions within 10 days after receipt of invoice.

Important: This is a binding registration and above fees are due in case of cancellation or non-appearance. If you cannot take part, you have to inform us in writing. The cancellation fee will then be calculated according to the point of time at which we receive your message. In case you do not appear at the event without having informed us, you will have to pay the full registration fee, even if you have not made the payment yet. Only after we have received your payment, you are entitled to participate in the conference (receipt of payment will not be confirmed!)